

aqueous liquid to form a granulate having a phytase activity of at least 6,000 FTU/gram.

Each of the Examiner's claim rejections have been overcome as set forth immediately below.

THE REJECTIONS UNDER 35 U.S.C. §103(a)

- A. The Rejection of claims 18, 19, 26-28 and 31 over Nielsen *et al.* in view of Jacobsen *et al.*

The Examiner argues that Neilson *et al.* teaches an *Aspergillus* phytase containing granulate, although a granulate comprising an edible carbohydrate polymer is not taught. On the other hand, the Examiner argues that Jacobsen *et al.* teaches an enzyme-containing granulate comprising 2-40% cellulose, although a phytase-containing granulate is not taught. The Examiner argues that one of ordinary skill in the art would have been motivated to combine the two documents to achieve a phytase-containing granulate falling within the scope of the claims.

It is respectfully submitted that this line of reasoning is not correct for two reasons: firstly, it is submitted that one of ordinary skill in the art would not have been motivated to combine the two documents cited by the Examiner; and secondly, even if one of ordinary skill in the art were to combine the two documents in the fashion suggested by the Examiner, it would still not have been possible to achieve a phytase-containing granulate falling within the scope of the claims.

Turning to the first point in more detail, it is submitted that one of ordinary skill in the art would not have been motivated to combine Nielsen *et al.* with Jacobsen *et al.* as suggested by the Examiner. Although it can be argued that the two documents, broadly speaking, are both concerned with animal feeds that does not, on its own, imply that one of ordinary skill in the art would have combined them. Two issues should be borne in mind when considering whether one of ordinary skill would in reality have combined the two documents. Firstly, there must, as the Examiner acknowledges, have been motivation for combining the two documents. Secondly, it is not enough that two documents, in hindsight, could have been combined, rather it must be shown

that that is in reality what the skilled person would have done. See *In re Lee*, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002).

Nielsen *et al.* is directed to a method for improving the solubility of vegetable proteins. The method comprises treating a vegetable protein source with an efficient amount of one or more phytase enzymes, one or more proteolytic enzymes and one or more lipolytic enzymes. The document also relates to animal feed additives, which comprise a phytase and a proteolytic enzyme. The document does, as the Examiner rightly points out, suggest that the animal feed additive described therein may be in the form of a granulated enzyme product which can be mixed with feed components. However, the discussion of granulated products amounts to only one paragraph in the entire document (page 10 lines 16 to 21) and to one reference to such products in claim 30.

It can be seen that the entire thrust of Nielsen *et al.* is directed to improving the solubility of vegetable proteins and that the notion of granulating the feed additives described in the document is a minor and peripheral part of its teaching.

Jacobsen *et al.* relates to an enzyme-containing granulate, a so called T-granulate, which is coated with a coating agent comprising a high melting fat or wax and which is said to be useful as a fodder if it is steam treated and subsequently palletized. The cited document mentions the use of β -glucanases or α -amylases, although those references appear to be disclosed in the context of a discussion of the prior art. Cellulases P and T are also discussed in the examples. Thus, the discussion of particular enzymes comprises only a small part of the document and the primary teaching of the document is simply that a coated granulate can stabilize enzyme activity.

This analysis of the teaching of the two cited documents makes it clear that they relate to widely differing sorts of technology. It is submitted that it is unrealistic to suggest that one of

ordinary skill in the art would have combined the documents in the manner suggested by the Examiner. Firstly, one of ordinary skill in the art would have quickly concluded that they relate to different fields of technology and would not have considered them side-by-side. It is not plausible to suggest that one of ordinary skill in the art would have combined a document which concerns a method for solubilising vegetable proteins with a document which concerns the preparation of a coated granulate. Secondly, there was no motivation for one of ordinary skill in the art to have considered combining them. Neither document refers to any deficiencies in the teaching they provide and it is not clear therefore why one of ordinary skill would have been motivated to modify either document or to combine them. It is submitted that although it may be argued that one skilled in the art could have combined the two documents, it is submitted that, in reality, he/she would not have done so.

Even if it is supposed, for the sake of argument, that one of ordinary skill had combined Nielsen *et al.* and Jacobsen *et al.* in the fashion suggested by the Examiner (which it is submitted the skilled person would not have), that person would still not have arrived at a granulate falling within the scope of claim 18 or 19.

The Examiner appears to have construed claims 18 and 19 as product *per se* claims directed to phytase-containing granulates which have a phytase activity of at least 6000 FTU per gram. The Examiner argues that a combination of Neilson *et al.* and Jacobsen *et al.* teaches such a granulate and therefore that claims 18 and 19 are obvious over that combination of documents.

With respect, it is submitted that it is not the correct approach. Claim 18 is directed to "A phytase-containing granulate, prepared by a process...". Note that the claim is not directed to a phytase-containing granulate preparable by a process. Claim 19 is directed to "A granulate having a

phytase activity of at least 6000 FTU per gram comprising dried granules formed from...". Note that the claim is not directed to a granulate formable from particular components.

It is submitted that as a matter of plain English, the process limitation steps set out in claims 18 and 19 should be read into those claims and therefore that they may only be rendered unpatentable by teaching of a phytase-containing granulate prepared by the process set out in claim 18 or formed from the components set out in claim 19. A combination of the teaching of Neilson et al. and Jacobsen et al. does not teach such granulates and therefore claims 18 and 19 are indeed patentable over that combination of documents.

Claim 18 requires that the phytase-containing granulate to which it is directed is prepared by a process comprising the steps of:

- (a) providing a solid carrier comprising at least about 15%(w/w) of an edible carbohydrate polymer;
- (b) providing an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid; and
- (c) mixing the solid carrier and the aqueous liquid to form a granulate having phytase activity of at least 6000 FTU per gram.

Neilson et al. does not teach providing a solid carrier comprising at least about 15% (w/w) of an edible carbohydrate polymer: it merely suggests that the animal feed additive it describes may be in the form of a granulated enzyme product. Furthermore, Neilson et al. does not directly and unambiguously disclose an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid. Phytase enzymes are discussed at page 6 line 12 to page 7 line 10 of the application, but an aqueous liquid comprising phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid is not directly and ambiguously disclosed within that

passage. The passage does of course refer to particular methods for preparing phytase enzymes, but does not disclose what concentrations of phytase may be achieved by those methods. There is a reference to phytase activities in the paragraph immediately following the passage referred to above, but that paragraph (page 7 line 11 to 16) refers to the amount of phytase which must be added per kilogram of vegetable protein source. Finally, Neilson *et al.* does not teach mixing a solid carrier and an aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram. The Neilson *et al.* document refers to particular amounts of phytase activities present in the animal feed additive (page 11 lines 27 to page 12 line 5). However, that disclosure appears in the context of a discussion of the animal feed additive itself, which is a preparation of a phytase and a proteolytic enzyme, not a granulated product. Thus, it can be seen that Neilson *et al.* does not disclose the features set out in claim 18.

Jacobsen *et al.* does arguably teach providing a solid carrier comprising about 15% (w/w) of an edible carbohydrate polymer, in that it teaches the use of 2-40% finely divided cellulose fibres at page 2 line 15. However, the document does not teach providing an aqueous liquid comprising a phytase concentration of at least 14,000 FTU per gram of an aqueous liquid and it cannot therefore teach mixing a solid carrier and an aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram.

On the basis of these arguments, it is submitted that a combination of Neilson *et al* and Jacobsen *et al* cannot be used to achieve a granulate falling within the scope of claim 18. That is primarily because neither of those documents directly and unambiguously disclose the provision of an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid. Therefore, it is submitted that claim 18 is indeed patentable in view of a combination of Neilson *et al.* and Jacobsen *et al.*

A similar argument is advanced in respect of claim 19. That claim requires that a granulate having a phytase activity of at least 6000 FTU per gram is formed from an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid and a solid carrier which comprises at least about 15% (w/w) of an edible carbohydrate polymer. As has been set out above in respect of claim 18, neither of the documents cited by the Examiner directly and unambiguously discloses an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid. Therefore, a combination of the two documents cited by the Examiner cannot teach a granulate falling within the scope of claim 19 and it is submitted that claim 19 is indeed patentable in view of that combination of documents. The remainder of the claims rejected by the Examiner under this paragraph, namely claims 26 to 28 and 31, are dependent on claim 18 or 19. Therefore the same arguments apply to those claims as have been advanced in respect of claims 18 or 19 and, on that basis, it is submitted that claims 26 to 28 and 31 are similarly patentable in view of a combination of Neilson et al. and Jacobsen et al.

B. The Rejection of claims 18 and 20 over Nielsen et al. in view of Jacobsen et al.

The Examiner rejected claims 18 and 20 over Nielsen et al. in view of Jacobsen et al. In addition to the Examiner's arguments above, the Examiner argues that Jacobsen et al. further teach the use of a coating agent comprising the divalent metals magnesium or calcium.

Applicant incorporates, herein by reference, the arguments above regarding claims 18 and 19. It is submitted that claim 18 is patentable in view of that combination of documents for the reasons set out above. Claim 20 is dependent on claim 19. It is

submitted that claim 19 is patentable over the two documents cited by the Examiner for reasons set out above and therefore that claim 20 is patentable for those same reasons.

C. The Rejection of claims 21-23 over Nielsen *et al.* in view of Jacobsen *et al.* as applied to claim 19 above, and further in view of Markussen *et al.* (U.S. Patent No. 4,106,991)

The Examiner rejected claims 21-23 over Nielsen *et al.* in view of Jacobsen *et al.* as applied to claim 19 above, and further in view of Markussen *et al.* (U.S. Patent No. 4,106,991). In addition to the Examiner's arguments above, the Examiner argues that Markussen *et al.* teach enzyme containing granulates comprising carboxymethyl cellulose as a binder for granulation.

It is submitted, for the reasons set out above and incorporated herein by reference, that claim 19 is in fact patentable over a combination of Neilson *et al.* and Jacobsen *et al.* and therefore that claims 21 to 23 are similarly patentable (for the same reasons) over the combination of three documents cited by the Examiner. The fact that Markussen *et al.* teaches derivitised cellulose is irrelevant to the patentability of claims 21 to 23 if claim 19 is patentable over a combination of Neilson *et al.* and Jacobsen *et al.* It is respectfully submitted that that is indeed the case.

D. The Rejection of claims 19 and 24 over Nielsen *et al.* in view of Jacobsen *et al.*

The Examiner rejected claims 19 and 24 over Nielsen *et al.* in view of Jacobsen *et al.* as applied to claim 19 above. Additionally, the Examiner argues that Nielsen *et al.* further teach phytase-containing feed additive comprising additional glucosidase enzymes such as xylan-endo-1,3-beta-xylosidase and endo-1,6-beta-glucanase.

It is submitted that claim 19 is patentable over that combination of documents for reasons set out above and incorporated herein by reference. Claim 24 is dependent on claim 19 and it is submitted therefore that claim 24 is similarly patentable over Neilson et al. and Jacobsen et al.

E. The Rejection of claims 19 and 25 over Nielsen et al. in view of Jacobsen et al.

The Examiner rejected claims 19 and 24 over Nielsen et al. in view of Jacobsen et al. as applied to claim 19 above. Additionally, the Examiner argues that Nielsen et al. further teach phytase-containing feed additive comprising additional glucosidase enzymes such as xylan-endo-1,3-beta-xylosidase and endo-1,6-beta-glucanase.

It is submitted that claim 19 is patentable over that combination of documents for the reasons set out above and incorporated herein by reference. Claim 25 is dependent on claim 19 and it is submitted therefore that claim 25 is similarly patentable over Neilson et al. and Jacobsen et al.

F. The Rejection of claims 19, 21, 22, 25 and 39 over Nielsen et al. in view of Rokey et al. (U.S. Patent No. 5,480,673)

The Examiner rejected claims 19, 21, 22, 25 and 39 over Nielsen et al. in view of Rokey et al. (U.S. Patent No. 5,480,673). The Examiner argues that Nielsen et al. teach an Aspergillus phytase containing granulate comprising 10,000 FTU/gram where the enzyme is added after pelleting or extrusion of the feed. The Examiner further argues that Rokey et al. teaches extruded particle animal feed comprising soy oil and corn.

It is submitted that claim 19 is in fact patentable over that combination of documents for the reasons set out above, and incorporated herein by reference, in respect of Neilson *et al.* and Jacobsen *et al.*

Rokey *et al.* teaches an extruded animal feed containing soluble protein, but which does not contain an enzyme. It is highly unlikely that one of ordinary skill in the art person would have been motivated to combine Neilson *et al.* with Rokey *et al.* in the first instance. Furthermore, even if one skilled in the art were to combine the two documents in the manner suggested by the Examiner, he/she would still not achieve a granulate falling within the scope of claim 19.

As has been explained above, the process limitation of claim 19 of forming a granulate from an aqueous liquid comprising phytase at a concentration of at least 14000 FTU per gram of aqueous liquid and a solid carrier which comprises at least about 15% (w/w) of an edible carbohydrate polymer is not taught by Nielsen *et al.* Similarly, it is not taught by Rokey *et al.* In particular, neither document directly and unambiguously discloses an aqueous liquid comprising a phytase of the concentration required by claim 19. Thus, the skilled person is unable to achieve a granulate falling within the scope of claim 19 on the basis of Neilson *et al* and Rokey *et al* and therefore it is submitted that claim 19 is indeed patentable over that combination of documents.

Claim 25 is dependent upon claim 19 and it is submitted therefore that claim 25 is similarly patentable over a combination of Neilson *et al.* and Rokey *et al.*.

G. The Rejection of claims 18 and 31-35 over Nielsen *et al.* in view of Jacobsen *et al.*

The Examiner rejected claims 18 and 31-35 over Nielsen *et al.* in view of Jacobsen *et al.* as applied to claim 18 above. The Examiner further argues that Nielsen *et al.* teaches a feed composition comprising a phytase feed additive and animal feed substances.

It is submitted that claim 18 is patentable for the reasons set out above, and incorporated herein by reference, and that claims 31 to 35 which are dependent upon claim 18 are therefore similarly patentable.

H. The Rejection of claims 21, 22, 39 and 40 over Nielsen *et al.* in view of Jacobsen *et al.* as applied to claim 19 above, and further in view of Aulik *et al.* (U.S. Patent No. 4,959,240)

The Examiner rejected claims 21, 22, 39 and 40 over Nielsen *et al.* in view of Jacobsen *et al.* as applied to claim 19 above, and further in view of Aulik *et al.* (U.S. Patent No. 4,959,240). In addition to the Examiner's arguments above, the Examiner argues that Aulik *et al.* teach the use of hydroxypropylmethyl cellulose as an agent to control the structural properties of the food.

Claims 21, 22, 39 and 40 are dependent on claim 19 and include the further limitation of the granulate comprising soy oil, canola oil or hydroxypropylmethyl cellulose. The Examiner points out that Aulik *et al.* teaches the use of soy or canola oil as lubricating components in the preparation of processed foods and the use of hydroxypropylmethyl cellulose as an agent to control the structural properties of foods.

However, if claim 19 is patentable over a combination of Neilson *et al.* and Jacobsen *et al.* the teaching of Aulik *et al.* is irrelevant. It is submitted that claim 19 is patentable over a combination of Neilson *et al.* and Jacobsen *et al.*, for the reasons set out above and incorporated herein by reference. Therefore claims 21, 22, 39 and 40, which are dependent upon claim 19, are similarly patentable.

In view of the arguments above, it is believed that pending claims 18-28, 31-35, 39 and 40 are allowable and that all rejections should be withdrawn.

Favorable reconsideration and allowance of the pending claims is, therefore,
courteously solicited.

Respectfully submitted,

**McDonnell Boehnen
Hulbert & Berghoff**

Dated: 3/25/02 By:


Alison J. Baldwin
Reg. No. 48,968